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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,226	07/10/2006	Christian Kaps	S-0959-US	2239

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
08/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,226	KAPS ET AL.	
	Examiner	Art Unit	
	STEPHEN GUCKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-43* is/are pending in the application.

4a) Of the above claim(s) *24,25,27,30,31,35,38 and 41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23,26,28-29,32-34,36-37,39-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I and the species CXCL7 and CXCL9 in the reply filed on 5/28/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 24-25, 27, 30-31, 35, 38 and 41-43 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/28/09.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: it list PCT/US2004/007581 as the international application that is the basis for the instant U.S. application. The correct international application is PCT/EP04/07581.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 21-23, 26, 28-29, 32-34, 36-37, and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or

use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims: The claims are directed to methods for producing a pharmaceutical preparation from a chemokine known as CXCL7, also known as pro-platelet basic protein, or PPBP, either alone or in combination with another chemokine, CXCL9. CXCL9 is also known as monokine induced by gamma interferon (MIG). The instant claims and the specification define the nature of the invention as a pharmaceutical therapeutic, such as for forming tissues (claim 23). Other uses include recruiting stem cells for tissue formation (claim 32), for injection (claim 33), for chondrogenesis or osteogenesis (claim 36), as a substrate for transplantation, a matrix, a tissue patch, or suture material (claim 40). The breadth of the claims is very wide, encompassing all fragments and derivatives capable of binding to a chemokine receptor.

It is recognized in patent law that an enabling teaching of how to use an invention directed to a method of isolating or making a preparation must include an enabling teaching of how to use the preparation isolated or made by the method. See *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689 (US SupCt 1966)(“We find absolutely no warrant for the proposition

that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself"). Therefore, the enabling disclosure must teach the skilled artisan how to use the preparation as asserted in the application.

In the instant case, the specification contemplates pharmaceutical and therapeutic use for preparations made by the methods presently claimed.

State of the prior art and level of predictability in the art: The art provides no guidance with respect to how to use CXCL7 either alone or with CXCL9 to accomplish any of the objectives set forth in the nature of the invention above. What the art does teach, however, is the involvement of SK2 channels in neuropathic pain or the use of agents that alter an expression value of SK2 channels in the treatment of neuropathic pain. However, the art does teach that therapeutic manipulation of CXCL7 with or without CXCL9 is likely to be complex and difficult. For example, although CXCL7 is released from platelets following their activation, Murphy et al. (IDS filed 10/2/07; "Murphy") teaches that

> Chemokine receptors comprise a large family of seven transmembrane domain G protein-coupled receptors differentially expressed in diverse cell types. Biological activities have been most clearly defined in leukocytes, where chemokines coordinate development, differentiation, anatomic distribution, trafficking, and effector functions and thereby regulate innate and adaptive immune responses. Pharmacological analysis of chemokine receptors is at an early stage of development. Disease indications have been established in human immunodeficiency virus/acquired immune deficiency syndrome and in *Plasmodium vivax* malaria, due to exploitation of CCR5 and Duffy, respectively, by the pathogen fro cell entry. Additional indications are emerging among inflammatory and immunologically mediated diseases, but selection of targets in this area still remains somewhat speculative. Small molecule antagonists with

> nanomolar affinity have been reported for 7 of the 18 known chemokine receptors but have not yet been studied in clinical trials (abstract).

Although the above excerpt is drawn to the chemokine receptors *per se*, the chemokine ligands perform their biological functions by binding to their receptors, so the discussion above is on point for the chemokine themselves. Thus, the art relevant to actually using the chemokines of the instant invention is undeveloped, and since it is a complex biological system with many competing interactions, the invention is innately unpredictable as well.

Amount of direction provided by the inventor and existence of working examples: There are no working examples provided for either CXCL7 or CXCL9 preparations in relation to any of the claimed uses. As a matter of fact, there are no working examples of either CXCL7 or CXCL9 preparations at all. No particular or specific guidance is drawn to either CXCL7 or CXCL9 preparations, only a general discussion concerning the multitude of chemokines found within the instant application.

Thus, the disclosure provides no validation that a method comprising producing a pharmaceutical preparation using CXCL7 alone or together with CXCL9 is useful in the treatment or manipulation of any of the recited uses.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is high, the skilled artisan would not be able to make and use the invention as asserted in the application without undue experimentation to establish CXCL7 alone or in combination with CXCL9 as a pharmaceutical preparation is a valid therapeutic for any of the uses recited. As observed by Murphy et al.,

translating the properties of chemokines into practical clinical terms and using such translations for therapeutic interventions has been difficult.

Given this high degree of unpredictability and the absence of any evidence to indicate that the pharmaceutical preparations of made by the methods of the instant invention are effective in treating or altering the course of any biological process for the claimed intentions is no more than a theoretical possibility. This is not sufficient to meet the enablement requirement of 35 USC §112, first paragraph[1].

In view of the foregoing, using the invention as contemplated in the specification would require undue experimentation. Therefore, the claims are properly rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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[1] Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. *Genentech Inc. v. Novo* Nordisk A/S (CA FC) 42 USPQ2d 1001, 1005.

a. Claims 21-23, 26, 28-29, 32-34, 36-37, and 39-40 are rejected under 35 U.S.C. 101 because the claimed methods do not have a specific, substantial, or well-known use as set forth in the rejection under 35 U.S.C. § 112, 1st paragraph above. The instant invention does not have a specific utility because any chemokine of any cell could be made into a preparation for the stated purposes, as demonstrated by the large numbers of species listed in the withdrawn claims that are all asserted to be useful for the same exact purposes recited in the dependent claims. Because substantial further research would have to be performed to determine if the claimed methods could be used to make useful pharmaceuticals for the recited purposes, the asserted utility is not substantial. The asserted uses of the instant invention is not enabled as set forth in the rejection under 35 U.S.C. § 112, 1st paragraph above. Finally, the art of record indicates that the subject matter of the instant invention does not have a well-known use in the real world. For these reasons, the claims are properly rejected under 35 USC §101 for lacking utility.

b.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21-23, 26, 28-29, 32-34, 36-37, and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The method claims are indefinite because they do not recite any positive active process steps by which the metes and bounds of the claimed methods could be established. The claims are written in a manner more suitable for product claims than they are for process claims.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

August 7, 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649